

| | | | |
|--|----------------------|----------------------------|------|
| TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i> | Application Number | 10/715,976 | |
| | Filing Date | November 17, 2003 | |
| | First Named Inventor | Samuel C. Wadsworth et al. | |
| | Art Unit | 1614 | |
| | Examiner Name | Not yet assigned | |
| Total Number of Pages in This Submission | 9 | Attorney Docket Number | 5121 |

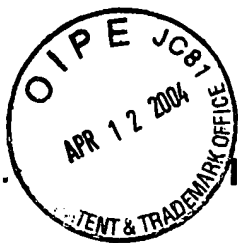
| ENCLOSURES (check all that apply) | | |
|--|---|--|
| <input type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input checked="" type="checkbox"/> CD, Number of CD(s) <u>1</u> | <input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): 5 pages of PTO-1449; 43 publications |
| Remarks | | |

| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | |
|--|------------------------|
| Firm or Individual name | Jennifer D. Tousignant |
| Signature | |
| Date | April 8, 2004 |

| CERTIFICATE OF MAILING | | | |
|---|----------------|------|---------------|
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. | | | |
| Typed or printed name | Michele Silver | | |
| Signature | | Date | April 8, 2004 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:

Samuel C. Wadsworth et al.

Examiner: Unassigned

Serial No.: 10/715,976

Group Art Unit: 1614

Filing Date: November 17, 2003

For: **METHODS OF TREATING DIABETES AND OTHER
BLOOD SUGAR DISORDERS**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

CERTIFICATE OF MAILING: Date of Deposit: April 8, 2004

I hereby certify under 37 CFR 1.8(a) that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313

MICHELE SILVER

Printed name of person mailing correspondence

Michele Silver

Signature of person mailing correspondence

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement is filed:

- ☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- ☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.
- ☒ Before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).

This Information Disclosure Statement is filed:

- ☐ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever comes first, and the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for the fee (\$180.00) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.

This Information Disclosure Statement is filed:

- ☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 more than three months prior to the filing of this Information Disclosure Statement.

II. Copies of the Cited Items:

- ☒ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
- ☐ Copies of only the following items listed on the attached Form PTO-1449 are not enclosed:
- ☐ Copies of those items which are marked with an asterisk (*) in the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. _____

filed _____ and relied upon in this application for an earlier filing date under 35 U.S.C. § 120. See 37 C.F.R. § 1.98(d).

- ☐ Copies of those items which are marked with an asterisk (**) in the attached Form PTO-1449 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

III. Concise Explanation of Relevance:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. **07-1074** for any additional fees required in connection with the filing of this Information Disclosure Statement.

Respectfully submitted,

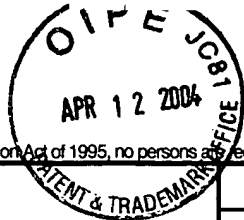
April 8, 2004

Date

By: 

Jennifer D. Tousignant
Agent for Applicants
Registration No. 54,498

Genzyme Corporation
15 Pleasant Street Connector
P.O. Box 9322
Framingham, Massachusetts 01701-9322
Telephone: (508) 270-2553
Facsimile: (508) 872-5415



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 5

Complete if Known

| | |
|------------------------|----------------------------|
| Application Number | 10/715,976 |
| Filing Date | November 17, 2003 |
| First Named Inventor | Samuel C. Wadsworth et al. |
| Art Unit | 1614 |
| Examiner Name | Not Yet Available |
| Attorney Docket Number | 5121 |

U.S. PATENT DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|------------------------|--------------------------|--|--------------------------------|--|---|
| | | Number - Kind Code ² (if known) | | | |
| | 1 | US-2002/0090719 | 07-11-2002 | Yew | |
| | 2 | US- 5,118,666 | 06-02-1992 | Habener | |
| | 3 | US- 5,264,618 | 11-23-1993 | Felgner et al. | |
| | 4 | US- 5,270,181 | 12-14-1993 | McCoy et al. | |
| | 5 | US- 5,283,185 | 02-01-1994 | Epand et al. | |
| | 6 | US- 5,334,761 | 08-02-1994 | Gebeyehu et al. | |
| | 7 | US- 5,364,771 | 11-15-1994 | Lollar et al. | |
| | 8 | US- 5,460,950 | 10-24-1995 | Barr et al. | |
| | 9 | US- 5,545,618 | 08-13-1996 | Buckley et al. | |
| | 10 | US- 5,563,045 | 10-08-1996 | Pittman et al. | |
| | 11 | US- 5,670,488 | 09-23-1997 | Gregory et al. | |
| | 12 | US- 5,753,500 | 05-19-1998 | Shenk et al. | |
| | 13 | US- 5,856,152 | 01-05-1999 | Wilson et al. | |
| | 14 | US- 5,882,877 | 03-16-1999 | Gregory et al. | |
| | 15 | US- 5,981,488 | 11-09-1999 | Hoffmann | |
| | 16 | US- 5,994,136 | 11-30-1999 | Naldini et al. | |
| | 17 | US- 6,013,516 | 01-11-2000 | Verma et al. | |
| | 18 | US- 6,191,102 | 02-20-2001 | DiMarchi et al. | |
| | | US- | | | |
| | | US- | | | |

FOREIGN PATENT DOCUMENTS

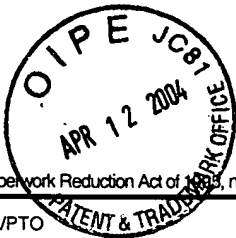
| Examiner Initials * | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|------------------------|--------------------------|---|-----------------------------------|---|--|----------------|
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | 19 | WO 95/06743 | 03-09-95 | Dong et al. | | |
| | 20 | WO 95/29993 | 11-09-95 | Nabel et al. | | |
| | 21 | WO 96/33280 | 10-24-96 | Zhang et al. | | |
| | 22 | WO 96/40955 | 12-19-96 | Graham et al. | | |
| | 23 | WO 97/00326 | 01-03-97 | Fallaux et al. | | |
| | 24 | WO 97/09441 | 03-13-97 | Wadsworth et al. | | |
| | 25 | WO 97/25446 | 07-17-97 | Kaleko et al. | | |
| | 26 | WO 99/57296 | 11-11-99 | Wadsworth et al. | | |

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08b(05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 5

Complete if Known

| | |
|------------------------|----------------------------|
| Application Number | 10/715,976 |
| Filing Date | November 17, 2003 |
| First Named Inventor | Samuel C. Wadsworth et al. |
| Group Art Unit | 1614 |
| Examiner Name | Not Yet Available |
| Attorney Docket Number | 5121 |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|--|----------------|
| | 27 | ABRUZZESE, Ronald V. et al., Ligand-Dependent Regulation of Plasmid-Based Transgene Expression in Vivo, Human Gene Therapy, Vol. 10, pp. 1499-1507 (June 10, 1999), Mary Ann Liebert, Inc. | |
| | 28 | ARGAUD, Doriane et al., Regulation of Rat Liver Glucose-6-Phosphatase Gene Expression in Different Nutritional and Hormonal States, Diabetes, Vol. 45, pp. 1563-1571 (November 1996) | |
| | 29 | AYALA, Julio E et al., Conservation of an Insulin Response Unit Between Mouse and Human Glucose-6-Phosphatase Catalytic Subunit Gene Promoters, Diabetes, Vol. 48, pp. 1885-1889 (September 1999) | |
| | 30 | BEHR, Jean-Paul et al., Efficient Gene Transfer into Mammalian Primary Endocrine Cells with Lipopolyamine-Coated DNA, Proc. Natl. Acad. Sci., USA, Vol. 86, pp. 6982-6986 (September 1989), Cell Biology | |
| | 31 | BOSSELMAN, Robert A., Replication-Defective Chimeric Helper Proviruses and Factors Affecting Generation of Competent Virus: Expression of Moloney Murine Leukemia Virus Structural Genes via the Metallothionein Promoter, Molecular and Cellular Biology, pp. 1797-1806 (May 1987), American Society for Microbiology | |
| | 32 | CHOW, Billy K.C. et al., Characterization of a Novel Liver-Specific Enhancer in the Human Prothrombin Gene, The Journal of Biological Chemistry, Vol. 266, No. 28, pp. 18927-18933 (October 5, 1991), The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 33 | CHRISTENSEN, Mads Tang et al., Glucagon-Like Peptide 1(7-36) Amide's Central Inhibition of Feeding and Peripheral Inhibition of Drinking are Abolished by Neonatal Monosodium Glutamate Treatment, Diabetes, Vol. 47, pp. 530-537 (April 1998) | |
| | 34 | CRISTIANO, Richard J. et al., Hepatic Gene Therapy: Efficient Gene Delivery and Expression in Primary Hepatocytes Utilizing a Conjugated Adenovirus-DNA Complex, Proc. Natl. Acad. Sci., USA, Vol. 90, pp. 11552, (December 1993), Genetics | |
| | 35 | CURIEL, David T. et al., Adenovirus Enhancement of Transferrin-Polylysine-Mediated Gene Delivery, Proc. Natl. Acad. Sci., USA, Vol. 88, pp. 8850-8854 (October 1991), Biochemistry | |
| | 36 | CUIF, Marie-Helene et al., Elements Responsible for Hormonal Control and Tissue Specificity of L-Type Pyruvate Kinase Gene Expression in Transgenic Mice, Molecular and Cellular Biology, pp. 4852-4861 (November 1992), American Society for Microbiology | |
| | 37 | DANOS, Olivier et al., Safe and Efficient Generation of Recombinant Retroviruses with Amphotropic and Ecotropic Host Ranges, Proc. Natl. Acad. Sci., USA, Vol. 85, pp. 6460-6464 (September 1988), Genetics | |

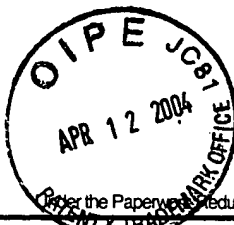
| | |
|-----------------------|--------------------|
| Examiner Signature | Date Considered |
|-----------------------|--------------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08b(05-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 5

Complete if Known

| | |
|------------------------|----------------------------|
| Application Number | 10/715,976 |
| Filing Date | November 17, 2004 |
| First Named Inventor | Samuel C. Wadsworth et al. |
| Group Art Unit | 1614 |
| Examiner Name | Not Yet Available |
| Attorney Docket Number | 5121 |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

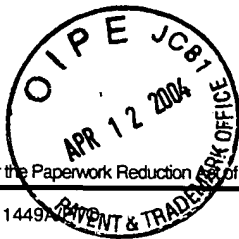
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|---|----------------|
| | 38 | EMBRETSON, Janet E. et al., Lack of Competition Results in Efficient Packaging of Heterologous Murine Retroviral RNAs and Reticuloendotheliosis Virus Encapsidation-Minus RNAs by the Reticuloendotheliosis Virus Helper Cell Line, <i>Journal of Virology</i> , pp. 2675-2683 (Sep. 1987), American Society for Microbiology | |
| | 39 | FEHMANN, Hans-Christoph et al., Insulinotropic Hormone Glucagon-Like Peptide-I(7-37) Stimulation of Proinsuline Gene Expression and Proinsuline Biosynthesis in Insulinoma BetaTC-1 Cells, <i>Endocrinology</i> , Vol. 130, No. 1, pp. 159-166 (1992), The Endocrine Society | |
| | 40 | FELGNER, Jiin H. et al., Enhanced Gene Delivery and Mechanism Studies with a Novel Series of Cationic Lipid Formulations, <i>The Journal of Biological Chemistry</i> , Vol. 269, No. 4, pp. 2550-2561 | |
| | 41 | FELGNER, Philip L. et al., Lipofection: A Highly Efficient, Lipid-Mediated DNA-Transfection Procedure, <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 84, pp. 7413-7417 (November 1987), Biochemistry | |
| | 42 | GREGORI, Claudine et al., Characterization of the Aldolase B Intronic Enhancer, <i>The Journal of Biological Chemistry</i> , Vol. 273, No. 39, pp. 25237-25243 (1998) The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 43 | GRIMM, Dirk et al., Novel Tools for Production and Purification of Recombinant Adenoassociated Virus Vectors, <i>Human Gene Therapy</i> , Vol. 9, pp. 2745-2760 (December 10, 1998), Mary An Liebert, Inc. | |
| | 44 | GOTTSCHALK, Stephen et al., Folate Receptor Mediated DNA Delivery into Tumor Cells: Potosomal Disruption Results in Enhanced Gene Expression, <i>Gene Therapy</i> , Vol. 1, pp. 185-191 (1994), Macmillan Press | |
| | 45 | GUERRA, MARIA-JOSE M. DIAZ et al., Functional Characterization of the L-Type Pyruvate Kinase Gene Glucose Response Complex, <i>Molecular and Cellular Biology</i> , Vol. 13, No. 12, pp. 7725-7733, American Society for Microbiology | |
| | 46 | JUMP, Donald B. et al., Thyroid Hormone and Dietary Carbohydrate Interact to Regulate Rat Liver S14 Gene Transcription and Chromatin Structure, <i>The Journal of Biological Chemistry</i> , Vol. 265, No. 6, pp. 3474-3478 (1990), The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 47 | KAYTOR, Elizabeth N. et al., Carbohydrate Regulation of Hepatic Gene Expression, <i>The Journal of Biological Chemistry</i> , Vol. 272, No. 11, pp. 7525-7531 (1997) The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 48 | KOCHANIEK, Stefan et al., A New Adenoviral Vector: Replacement of all Viral Coding Sequences with 28 kb of DNA Independently Expressing Both Full-Length Dystrophin and Beta-Galactosidase, <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 93, pp. 5731-5736 (June 1996) Medical Sciences | |

| | |
|-----------------------|--------------------|
| Examiner Signature | Date Considered |
|-----------------------|--------------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08b(05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

4

of

5

Complete if Known

| | |
|------------------------|----------------------------|
| Application Number | 10/715,976 |
| Filing Date | November 17, 2003 |
| First Named Inventor | Samuel C. Wadsworth et al. |
| Group Art Unit | 1614 |
| Examiner Name | Not Yet Available |
| Attorney Docket Number | 5121 |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|--|----------------|
| | 49 | KUPFER, Joel M., et al., High-Efficiency Gene Transfer to Autologous Rabbit Jugular Vein Grafts Using Adenovirus-Transferrin/Polylysine-DNA Complexes, Human Gene Therapy, Vol. 5, pp. 1437-1443 (December 1994), Mary Ann Liebert, Inc. | |
| | 50 | LEE, Hyun Chul et al., Remission in Models of Type 1 Diabetes by Gene Therapy Using a Single-Chain Insulin Analogue, Nature, Vol. 408, pp. 483-488 (November 23, 2000), Macmillan Magazines Ltd. | |
| | 51 | LOU, Dan-Qing et al., Chicken Ovalbumin Upstream Promoter-Transcription Factor II, a New Partner of the Glucose Response Element of the L-Type Pyruvate Kinase Gene, Acts as an Inhibitor of the Glucose Response, The Journal of Biological Chemistry, Vol. 274, No. 40, pp. 28385-28394 (1999) The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 52 | MARKOWITZ, Dina et al., A Safe Packaging Line for Gene Transfer: Separating Viral Genes on Two Different Plasmids, Journal of Virology, Vol. 62, No. 4, pp. 1120-1124 (Apr. 1988), American Society for Microbiology | |
| | 53 | MILLER, A. Dusty, Human Gene Therapy Comes of Age, Nature, Vol. 357, pp. 455-460 (June 11, 1992) | |
| | 54 | NAKAYAMA, Kazuhisa, Furin: A Mammalian Subtilisin/Kex2p-like Endoprotease Involved in Processing of a Wide Variety of Precursor Proteins, Biochem. J., Vol. 327, pp. 625-635 (1997) Printed in Great Britain | |
| | 55 | O'CALLAGHAN, Brennon L. et al., Glucose Regulation of the Acetyl-CoA Carboxylase Promoter PI in Rat Hepatocytes, The Journal of Biological Chemistry, Vol. 276, No. 19, pp. 16033-16039 (May 11, 2001) The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 56 | ROUET, Philippe et al., An Array of Binding Sites for Hepatocyte Nuclear Factor 4 of High and Low Affinities Modulates the Liver-Specific Enhancer for the Human Alpha1-Microglobulin/Bikunin Precursor, Biochem. J., Vol. 334, pp. 577-584 (1998) Printed in Great Britain | |
| | 57 | RUFO, Caterina et al., Involvement of a Unique Carbohydrate-Responsive Factor in the Glucose Regulation of Rat Liver Fatty-Acid Synthase Gene Transcription, The Journal of Biological Chemistry, Vol. 276, No. 24, pp. 21969-21975 (2001) The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 58 | SABOURIN, Jean-Christophe et al., An Intronic Enhancer Essential for Tissue-Specific Expression of the Aldolase B Transgenes, The Journal of Biological Chemistry, Vol. 271, No. 7, pp. 3469-3473, (February 16, 1996) The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 59 | SALVETTI, Anna et al., Factors Influencing Recombinant Adeno-Associated Virus Production, Human Gene Therapy, Vol. 9, pp. 695-706 (March 20, 1998), Mary Ann Liebert, Inc. | |

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08b(05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 5 of 5

Complete if Known

| | |
|------------------------|----------------------------|
| Application Number | 10/715,976 |
| Filing Date | November 17, 2003 |
| First Named Inventor | Samuel C. Wadsworth et al. |
| Group Art Unit | 1614 |
| Examiner Name | Not Yet Available |
| Attorney Docket Number | 5121 |

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|------------------------|--------------------------|---|----------------|
| | 60 | THOMPSON, Kimberly et al., Localization of the Carbohydrate Response Element of the Rat L-Type Pyruvate Kinase Gene, The Journal of Biological Chemistry, Vol. 266, No. 14, pp. 8679-8682 (May 15, 1991) The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 61 | THULE, PM et al., Regulated Hepatic Insulin Gene Therapy of STZ-Diabetic Rats, Gene Therapy, Vol. 7, pp. 1744-1752 (2000) Macmillan Publishers Ltd. | |
| | 62 | WAGNER, Ernst et al., Coupling of Adenovirus to Transferrin-Polylysine/DNA Complexes Greatly Enhances Receptor-Mediated Gene Delivery and Expression of Transfected Genes, Proc. Natl. Acad. Sci. USA, Vol. 89, pp. 6099-6103 (July 1992) Biochemistry | |
| | 63 | WATANABE, Shinichi et al., Construction of a Helper Cell Line for Avian Reticuloendotheliosis Virus Cloning Vectors, Molecular and Cellular Biology, pp. 2241-2249 (December 1983) American Society for Microbiology | |
| | 64 | WU, George Y. et al., Incorporation of Adenovirus into a Ligand-Based DNA Carrier System Results in Retention of Original Receptor Specificity and Enhances Targeted Gene Expression, The Journal of Biological Chemistry, Vol. 269, No. 15, pp. 11542-11546 (April 15, 1994) The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 65 | YOSHIMURA, Kunihiro et al., Adenovirus-Mediated Augmentation of Cell Transfection with Unmodified Plasmid Vectors, The Journal of Biological Chemistry, Vol. 268, No. 4, pp. 2300-2303 (1993) | |
| | 66 | SCHMOLL, Dieter et al., Cloning and Sequencing of the 5' Region of the Human Glucose-6-Phosphatase Gene: Transcriptional Regulation by cAMP, Insulin and Glucocorticoids in H4IIE Hepatoma Cells, FEBS Letters, Vol. 383, pp. 63-66 (1996) | |
| | 67 | SHIH, Hsiu-Ming et al., Two CACGTC Motifs with Proper Spacing Dictate the Carbohydrate Regulation of Hepatic Gene Transcription, The Journal of Biological Chemistry, Vol. 270, No. 37, pp. 21991-21997 (September 15, 1995) The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 68 | SHIH, Hsiu-Ming et al., Definition of the Carbohydrate Response Element of the Rat S14 Gene, The Journal of Biological Chemistry, Vol. 269, No. 12, pp. 9380-9387 (March 25, 1994), The American Society for Biochemistry and Molecular Biology, Inc. | |
| | 69 | SOUZA, David W. et al., In Vivo Analysis of Muscle Specific Promoter Chimeras, Molecular Therapy, Vol. 5, No. 5, Part 2 of 2 Parts, #1255, S409 (May 2002) The American Society of Gene Therapy | |
| | | | |

| | |
|-----------------------|--------------------|
| Examiner Signature | Date Considered |
|-----------------------|--------------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.